Clinical trials of drugs

1919. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the new drug applications received during 2002;

(b) the number of the drugs for which clinical trials are being done alongwith the names of the Drugs, Companies and the Centre approved for the trial; and

(c) in which manner DCGI monitor the authenticity of such trials?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) During the year 2002, 1017 applications of various categories were received in the office of DCG(I) which includes application for New Unapproved Drugs (NDA)-189, Investigational New Drug applications (IND)-05 and remaining 823 applications for categories like subsequent New Drug applications (SNDA), New Bulk Drug, Fixed Dose Combination, Recombinant products, New Indications and New Dosage form etc.

(b) Information is being collected and will be laid on the table of the House.

(c) Clinical trial are required to be conducted by qualified clinical investigators as per Good Clinical Practice (GCP) guidelines and after due approval by Institutional Ethics Committee. The Ethics Committee are also required to follow "Ethical Guidelines for Biomedical Research on Human subjects" published by Indian Council of Medical Research.

Stock of medicines in CGHS

1920. SHRI MANOJ BHATTACHARYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether under existing system of supply of medicine, the CGHS dispensaries are authorized to keep stock of two hundred eighty varieties of medicines only;

(b) whether it is a fact that any drug prescribed by specialists outside the aforesaid varieties has to be initially purchased by the beneficiary and subsequently claimed for reimbursement;

(c) if so, whether Government are aware of undue hardship faced by the CGHS beneficiaries to get the refund; and

(d) if so, whether any alternative system is under consideration of Government and if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) No, Sir.

(b) to (d) No, Sir. Any drug prescribed by the Govt. Specialists, not available in the dispensary, is issued to the beneficiary after procuring the same from the Authorised Local chemist on the basis of the individual prescription of the beneficiary. In the case of emergency, an authority slip is issued to the beneficiary for collecting the medicine directly from the Authorised Local Chemist without making any payment.

Medical Colleges in J and K

1921. SHRI T.S. BAJWA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of Medical Colleges both private and Government owned in J&K; and

(b) the details of health standard of the population in J&K?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) There are four medical colleges in the State of J and K. Out of which three colleges are in Govt. sector and one in private sector.

(b) "Health" being State subject no such data is being maintained by the Central Government.

Used syringes and disposable medical equipments

1922. SHRI VIJAY J. DARDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a gang has been collecting used syringes and disposable medical equipments from hospitals and after cleaning, these are packed for supply to hospitals as reported in the Indian Express dated 10th January, 2003 and thereby becoming a health hazard;